

**REMARKS**

The specification on page 17, as originally filed, has been amended in accordance with the Office Action. The paragraph bridging pages 17 and 18 of the application, as originally filed, has been amended to note that Application Ser. No. 07/744,649 is abandoned. No new matter is added by this amendment.

Claims 1 to 4 are pending. Claim 5 is canceled. Claims 6 to 13 have been previously withdrawn by election in response to a Restriction Requirement. Claims 1 and 2 are herein amended.

Support for the amendment to claim 1 may be found throughout the application and, for example, in Examples 1, 5 and 8. Claim 2 has been amended, as requested by Supervisory Examiner Chan, to conform to the method of claim 1 from which claim 2 depends.

**A. INTERVIEW SUMMARY**

Applicant expresses his deep gratitude to Examiner Saunders and Supervisory Examiner Chan for the fruitful discussion provided during the Examiner Interview of January 23, 2007. Participants at the Examiner Interview were Examiner Saunders, Supervisory Examiner Chan, Teresa Lavenue and Daren Nicholson of Kenyon & Kenyon LLP. Although the interview summary form submitted by the Examiner indicated that a formal interview summary by the Applicant was not necessary, Applicant submits this summary.

During the interview, proposed claim amendments were discussed along with proposed arguments in support of the proposed amended claims and a proposed declaration under 37 C.F.R. § 1.132. No art was discussed and no exhibits were presented.

Concerning the above-captioned application, Applicant first discussed the amendments to claims 1 and 2 made herein. Applicant next discussed Applicant's position that claim 1 is enabled by the specification.

In support of the enablement of claim 1, Applicant's representative discussed that the specification provides one of skill in the art with methods for administering malignin to a subject sufficient to stimulate production of antimalignin antibody and directed the Examiner, for example, to Example 8 in the specification. Applicant's representative further discussed that the specification provides one of skill in the art with an understanding that antimalignin antibody

binds preferentially to glioma cells in brain tumors *in vivo* and directed the Examiner, for example, to Examples 1, 2 and 5. Applicant's representative further discussed that the specification provides one of skill in the art with an understanding that antimalignin antibody kills glioma cells by at least complement-dependent cytotoxicity in a serum assay *in vitro* and directed the Examiner, for example, to Example 5. Applicant's representative finally discussed that one of skill in the art would expect antimalignin antibodies produced *in vivo* to bind and kill glioma cells in a subject *in vivo*. Applicant's representative suggested that the inventor was willing to submit a 1.132 declaration in support of this conclusion.

Examiner Saunders and Supervisory Examiner Chan agreed that they would consider such a 1.132 declaration by the inventor. Applicant provides the discussed 1.132 declaration herewith.

#### **B. WITHDRAWAL OF OBJECTIONS AND REJECTIONS**

Applicant thanks the Examiner for withdrawing the previous objection to the specification and previous rejections of claim 1 to 5 in the Office Action of February 13, 2006, including rejections for indefiniteness, written description, and anticipation and obviousness over US 4,976,957 (Bogoch) and EP 0,015,078 (Bogoch), and over US 4,976,957 (Bogoch) in view of Chase.

#### **C. OBJECTION TO THE SPECIFICATION**

The Examiner has indicated that the current status of Application Serial No. 07/744,649 should be indicated in paragraph [029] of the substitute specification. *See* October 12, 2006 Office Action at 3. Applicant has amended the specification to provide the status of Application Serial No. 07/744,649 as "now abandoned." As such, Applicant respectfully requests the Examiner withdraw this objection to the specification.

#### **D. REJECTION OF CLAIMS 1 TO 5 UNDER 35 U.S.C. § 112, PARAGRAPH 1—ENABLEMENT**

The Examiner has maintained the rejection of claims 1 to 5 under 35 U.S.C. § 112, first paragraph, for enablement. Claim 5 has been canceled. The Applicant respectfully submits this obviates the rejection of claim 5 for enablement.

Applicant additionally respectfully submits claims 1-4 as amended are fully enabled. In support of this assertion, Applicant provides herewith a Declaration under 37 C.F.R. § 1.132 ("the 132 Declaration")(attached at Tab 2), in which Applicant declares that in his opinion, one of skill in the art would have been enabled on the date of priority of the present application to practice the claimed invention.

In the 132 Declaration, Dr. Bogoch declares that in his opinion, the above-captioned application would have enabled one of skill in the art to administer antimalignin antibody to kill glioma cancer cells within a subject *in vivo* on the priority date of the application because: (1) the present application teaches one of skill in the art how to subcutaneously administer malignin to produce antimalignin antibody *in vivo*, (2) the present application teaches that antimalignin antibody preferentially binds glioma cells in the brain *in vivo*, and (3) the present application teaches that antimalignin antibody kills glioma cells *in vitro* through at least complement-dependent cytotoxicity. Therefore, Applicant concludes that one of skill in the art would expect the production of antimalignin antibodies *in vivo* to preferentially bind and kill glioma cells *in vivo* with at least complement-dependent cytotoxicity and would find the present application highly suggestive of success in practicing such a method.

Dr. Bogoch further concludes in the 132 Declaration that one of skill in the art would expect antimalignin antibody to bind glioma tumor cells in the brain despite the presence of the blood-brain barrier because of leakiness caused by growth of a tumor and because of limited passage of antibodies across the blood-brain barrier. Dr. Bogoch further notes that research reports (since the priority date of the application) have confirmed the teachings of the application that antimalignin antibody would be expected to bind and kill glioma tumor cells with at least complement-dependent cytotoxicity despite the presence of the blood-brain barrier. Since it has been shown that antimalignin antibodies bind and kill cells at surprising low concentrations (picogram amounts) and that in addition to antimalignin antibodies, others have shown that other antibodies cross the blood brain barrier, antimaligin antibodies would likely be effective *in vivo* since only picogram amounts are effective.

Dr. Bogoch concludes, therefore, that the above-captioned application would have enabled one of skill in the art to administer antimalignin antibody to kill glioma cancer cells within a subject *in vivo* because: (1) the present application teaches one of skill in the art how to

subcutaneously administer malignin to produce antimalignin antibody *in vivo*, (2) the present application teaches that antimalignin antibody preferentially binds glioma cells in the brain *in vivo*, and (3) the present application teaches that antimalignin antibody kills glioma cells *in vitro* through at least complement-dependent cytotoxicity.

Dr. Bogoch further concludes that one of skill in the art would expect the production of antimalignin antibodies *in vivo* to preferentially bind and kill glioma cells *in vivo* with at least complement-dependent cytotoxicity and would find the present application highly suggestive of success in practicing such a method.

Dr. Bogoch finally concludes that because one of skill in the art could have followed the detailed description in Example 8 of the application and would have found data disclosed in the application indicative of success in following the description in Example 8, one of skill in the art would not require undue experimentation to practice the invention based on the present application.

In view of Applicant's enablement of the claims as amended and the Applicant's 132 Declaration submitted herewith, Applicant respectfully requests the Examiner withdraw the rejection of claims 1 to 4.

**E. REJECTION OF CLAIM 5 UNDER 35 U.S.C. § 102(b)—ANTICIPATION**

The Examiner has asserted a new rejection of claim 5 as anticipated by US 4,840,915 (Bogoch). Applicant has canceled claim 5 and respectfully submits the rejection is obviated. Applicant respectfully requests the rejection be withdrawn.

**CONCLUSION**

It is believed that the present claims are in condition for allowance and Applicant earnestly requests the same.

An early and favorable action on the merits is earnestly solicited.

**Docket No: 13793/46702, formerly 09425/46702**

**Application No: 09/854,568**

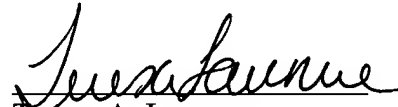
**Response to Office Action**

The Examiner is invited to contact the undersigned attorney if necessary to expedite allowance.

The Commissioner is authorized to charged any fees or overpayments associated with this application to Kenyon & Kenyon LLP **Deposit Account No. 11-0600.**

Respectfully submitted,

KENYON & KENYON LLP



Teresa A. Lavenue

Reg. No. 47,737

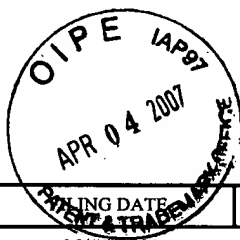
Dated: April 4, 2007

1500 K Street, N.W.  
Suite 700  
Washington, DC 20005  
Telephone: 202/220-4200  
Facsimile: 202/220-4201  
Customer No. 23838



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov



APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/854,568

05/15/2001

Samuel Bogoch

9425/46702

8438

7590  
KENYON & KENYON  
Suite 700  
1500 K Street, N.W.  
Washington, DC 20005

01/31/2007

EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

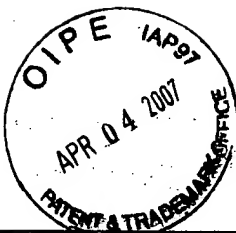
MAIL DATE

DELIVERY MODE

01/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARK  
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
--------------------	-------------	-----------------------	---------------------

854,568 BOGOCH

EXAMINER
----------

D. SAUNDERS

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED:

INTERVIEW SUMMARY

All participants (applicant, applicant's representative, PTO personnel):

(1) TERESA LA VENUE (3) DAVID SAUNDERS

(2) DAREN NICHOLSON (4) CHRISTINA CHAN

Date of Interview 8/23/07

Type: ☐ Telephonic ☐ Televideo Conference ☒ Personal (copy is given to ☐ applicant ☒ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No If yes, brief description:

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: 2, 5

Identification of prior art discussed: BOGOCH (4,840,915)

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: APPLICANT URGED THAT ANTI-MALIGNIN ABS KILL CELLS IN VITRO THAT INJECTION OF MALIGNIN INDUCES ABS IN VIVO (EX 8) AND THAT IV INJECTED ABS LOCALIZE TO BRAIN (EX 2). APPLICANT TO FURTHER PRESENT DECLARATION RE REASONS FOR LACK OF UNDUE EXPERIMENTATION. APPLICANT TO FURTHER CONSIDER COMPOSITION CLAIM 5 WITH RESPECT TO PRIOR ART. APPLICANT TO AMEND CLAIM 2 FROM A "PROCESS" TO A --METHOD-- CLAIM.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary. A FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

Examiner Note: You must sign this form unless it is an attachment to another form.

David A Saunders